

# ER/DL SPL Team Meeting

## Minutes - November 10, 2010

**Chair of today's meeting:** Pat Cowall-Hanover

**Next scheduled meeting:** Dec 8, 2010

### **Teleconference numbers:**

Telephone number: 866-217-3840

Access code: 897 2163

### **Topics discussed**

1. Images to include in SPL file: We received a call from the FDA last week informing us that a product was not listed on the NDC Directory and was not completely drug listed because we only had a package label in the PDP section for 1 of 2 product codes listed in the SPL. I shared with them that we've been given guidance to file a representative sampling and we have not been given a qualifier. The gentleman informed me that we need to list an image for EACH product code. I wanted to discuss this with the group to see if anyone has heard something similar and determine where to go from there. Jackie Mohns (BMS)
  - In 21CFR207.25.B(2) –“differences only exist in the quantity statement”
  - BMS will start submitting 1 per product code.
  - Lilly reported that they are providing 1 per strength. The above statement is not necessarily applicable to all products. For insulins, we are providing 1 per formulation – where we have different product codes for vials, cartridges, pens.
  - Our recommendation is 1 image per formulation/strength. This is typically considered 1 image per product code, but there are exceptions (eg insulins).
    - And, only one level of packaging – not both container and carton.
  - Disclaimer
    - This is our understanding at this time
    - There could be some variability in the review by DRLS because this is a manual check.
2. Interesting observation: Got an automated error message with a suggestion that the data should be changed to a different data value.
  - It appears that somebody actually looked at the file and had suggested the correction.
3. How to other companies handle sending SPL to the registration after it has been eListed. Mike (BI)
  - It is not required to submit SPL to the “agency”. The approval letters are now telling sponsors to submit to eList.
  - Send link with the URL in eList within annual report.
4. API. We list APIs in their own SPL. Do other companies
  - Many sponsors are submitting APIs separately.
  - Paul Loebach (DRLS) suggested that APIs be listed separately.
  - How do you drug listing bulk intermediate -- API that is not 100% pure?

- Kathy Olger: list the bulk intermediate manufacturing site in the list of establishments for the final drug product.

5. Hypromelloses? Pat

- The name changed to add an “s,” and SPLs that use the old name (without an “s”) are failing validation.
- Why was the “s” added? We have asked Lonnie. He is developing an answer and will tell us soon. Work in progress – no date.

6. OTC subteam meeting – discussion session with Lonnie and Import staff

- Rescheduled for Monday, Dec 13, 1 pm. See wiki for telephone call in information.
- Please send questions in advance to Marcia Howard, so that she can forward them to Lonnie.
- Topics: Listing inactive ingredients, import issues

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**In Process topics:**

- Arranging a discussion at a future meeting with someone at CMS -- to discuss how CMS interacts with drug listing (Pat and Terry)
- Terry created a space on wiki to collect questions for future discussions with FDA: DRLS and SPL.
- Process for export products ( Pat/Jean)
- Rationale for why it is difficult to have R3s removed manually from Daily Med (Howard/Jean/Pat)
- Communicating with FDA about validation errors – that result in issues with import, not being able to be compliant with instructions in approval letters, etc. (Warren, Jean, Dragan, and Jessica)